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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,904

09/30/2003

Cecil Kost

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05/23/2005

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EXAMINER

LAstra, DANIEL

ART UNIT

PAPER NUMBER

3622

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,904

Applicant(s)

KOST ET AL.

Examiner

DANIEL LASTRA

Art Unit

3622

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03/14/2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10,16-25,31-45 and 51-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,16-25,31-45 and 51-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/06/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Claims 1-10, 16-25, 31-45 and 51-55 have been examined. Application 10/674,904 has a filing date 09/30/2003 and Claims Priority from Provisional Application 60/472,956 (05/22/2003).

### ***Response to Amendment***

2. In response to Requirement for Restriction/Election action filed 01/31/2005, the Applicant filed an Amendment (03/14/2005) that elect group I for prosecution on the merits. Applicant amended claims 16, 34, cancel claims 11-15, 26-30, 46-50 and added new claims 51-55.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of: (1) whether the invention is within the technological arts; and (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory

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subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, the instant claims fail to recite the use of any type of technology (e.g. computer system) within the recited steps of a system for promoting pharmaceutical drugs.

Mere intended or nominal use of a component, albeit within the technological arts, does not confer statutory subject matter to an otherwise abstract idea if the component does not apply, involve, use, or advance the underlying process.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result.

Although the claimed invention produces a useful, concrete and tangible result, since the claimed invention as a whole is not within the technological arts, as explained above, claims 1-3 and 5 are deemed to be directed to non statutory subject matter.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 16-25, 31-45 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Feeney (US 2002/0032582).

As per claim 1, Feeney teaches:

A system for promoting pharmaceutical drugs, comprising:

a set of brand rules for guiding a distribution of drug samples of a drug (see paragraph 37; 274-275); and

a drug sample fulfillment platform for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative (see paragraphs 118, 216, 239, 241, 257-260, 282-284).

As per claim 2, Feeney teaches:

The system of Claim 1, wherein drug samples include physical samples (see paragraph 246).

As per claim 3, Feeney teaches:

The system of Claim 1, wherein drug samples include a pad of pre-printed vouchers (see paragraph 118).

As per claim 4, Feeney teaches:

The system of Claim 1, wherein drug samples include a coupon printed in the office of the prescriber, which is networked to the drug sample fulfillment platform (see paragraph 282).

As per claim 5, Feeney teaches:

The system of Claim 1, wherein the drug samples, which are in a printed form, are redeemable at a pharmacy, redeemed data being generated by the drug sample fulfillment platform for refining the brand rules so as to better guide distribution of the drug samples (see paragraph 282-284).

As per claim 6, Feeney teaches:

A system for distributing pharmaceutical drugs, comprising:

a drug sample fulfillment platform for accessing drug sample services (see paragraphs 258, 273); and

a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples (see paragraphs 258, 273).

As per claim 7, Feeney teaches:

The system of Claim 6, further comprising a second set of Web pages coupled to the drug sample fulfillment platform through which a sales representative can access the drug sample fulfillment platform to print coupons (see paragraph 284).

As per claim 8, Feeney teaches:

The system of Claim 6, further comprising a third set of Web pages coupled to the drug sample fulfillment platform through which a patient can access the drug sample fulfillment platform to obtain sample vouchers (see paragraph 118).

As per claim 9, Feeney teaches:

The system of Claim 6, wherein the first set of Web pages display a list of drug samples available to the prescriber to order drug samples in a form selected from a group consisting of physical samples, pre-printed vouchers, and print on-demand coupons (see paragraph 275, 284-285).

As per claim 10, Feeney teaches:

The system of Claim 6, wherein the first set of Web pages display a list of the order history of the prescriber, the list including a date and a drug sample ordered by the prescriber (see paragraphs 216, 290).

As per claim 16, Feeney teaches:

A drug sample fulfillment platform, comprising:

a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, an e-Detailing service, a Web site regarding a drug brand, and an online physician learning site (see paragraph 290); and

a request database for receiving requests of a prescriber through the drug sample Web site for drug samples, the request database responding to the prescriber by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers (see paragraphs 284, 118, 258-260).

As per claim 17, Feeney teaches:

The drug sample fulfillment platform of Claim 16, wherein the request database receives claim information when a patient redeems a print coupon or a preprinted voucher for physical samples (see paragraph 52).

As per claim 18, Feeney teaches:

The drug sample fulfillment platform of Claim 17, wherein the request database produces a first report accounting for the number of coupons or vouchers redeemed by patients of the prescriber (see paragraphs 274-275)

As per claim 19, Feeney teaches:

The drug sample fulfillment platform of Claim 18, wherein the request database produces a second report correlating an allocation of drug samples of a drug to the prescriber with the number of prescriptions written by the prescriber relating to the drug (see paragraph 275).

As per claim 20, Feeney teaches:

The drug sample fulfillment platform of Claim 19, wherein the request database produces a third report accounting for the monetary amount spent by a pharmaceutical company on a drug sample fulfillment program for a drug and a monetary amount associated with prescriptions written by the prescriber for the drug (see paragraphs 274-275).

As per claim 21, Feeney teaches:

A networked system for ordering pharmaceutical sample drugs, comprising:

a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink, the drug sample Web site presenting a Web page including selectable options for the prescriber to order drug samples (see paragraph 258-259, 284-285).

As per claim 22, Feeney teaches:

The networked system of Claim 21, wherein the drug samples are in a form selected from a group consisting of physical samples and pre-printed vouchers (see paragraphs 118 and 159).

As per claim 23, Feeney teaches:

The networked system of Claim 21, wherein the selectable options of the Web page include a quantity for each drug sample, which is specifiable by the prescriber (see paragraph 259).

As per claim 24, Feeney teaches:



The networked system of Claim 21, the selectable options of the Web page include a delivery location to which the drug samples will be shipped (see paragraph 111).

As per claim 25, Feeney teaches:

The networked system of Claim 21, wherein the selectable options of the Web page include an option for printing on-demand vouchers on a printer in the office of the prescriber (see paragraph 284).

As per claim 31, Feeney teaches:

A method for accessing a drug sample fulfillment platform, comprising:

activating a link to access the drug sample fulfillment platform from a Web portal (see paragraph 195); creating a transaction that includes a prescriber identifier and a partner identifier; and

mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples (see paragraphs 258-259; 284).

As per claim 32, Feeney teaches:

The method of Claim 31, further comprising formatting a set of Web pages of the drug sample Web site prior to the act of mating to emulate the look and feel of the Web portal (see paragraph 284).

As per claim 33, Feeney teaches:

The method of Claim 31, causing the prescriber to register if the prescriber identifier is not found in a request database (see paragraph 189).

As per claim 34, Feeney teaches:

The method of Claim 31, based on a segment to which the prescriber belongs, determining one or more of the following:

what drug samples that are available to the prescriber (see paragraphs 258-259; 284);

a drug sample quantity limit that is available to the prescriber (see paragraph 259);

a drug sample time limit in which the drug sample quantity limit is available (see paragraph 259); and the type of sample that is available to the prescriber (see paragraphs 258-259).

As per claim 35, Feeney teaches:

The method of Claim 34, receiving a selection for physical samples, the act of receiving including receiving a drug selection, a type of drug sample selection, a quantity of drug sample selection, and a delivery address (see paragraphs 258-259; 111).

As per claim 36, Feeney teaches:

The method of Claim 35, receiving a print request to print an order form capturing the drug selection, the type of drug sample selection, the quantity of drug sample selection, and the delivery address (see paragraph 219, 111).

As per claim 37, Feeney teaches:

The method of Claim 36, recording the requesting activities of the prescriber in a request database (see paragraph 275).

As per claim 38, Feeney teaches:

The method of Claim 34, receiving a selection for pre-printed vouchers or print coupons, the act of receiving including receiving a drug selection, and a quantity of coupons to be printed (see paragraphs 284-285).

As per claim 39, Feeney teaches:

The method of Claim 38, receiving a ship request to ship the pre-printed vouchers or a print request to print coupons capturing the drug selection (see paragraphs 118, 111, 284).

As per claim 40, Feeney teaches:

The method of Claim 39, recording the requesting activities of the prescriber in a request database (see paragraph 275).

As per claim 41, Feeney teaches:

The method of Claim 40, receiving a request to print a first report that lists registration data of the prescriber, the requesting activities of the prescriber, and the claim data from a claim processor that is indicative of redeemed pre-printed vouchers and print coupons at pharmacies (see paragraphs 274-275).

As per claim 42, Feeney teaches:

The method of Claim 40, receiving a request to print a second report that correlates drug samples of a drug distributed to the prescriber and with prescriptions written by the prescriber relating to the drug (see paragraphs 274-275).

As per claim 43, Feeney teaches:

The method of Claim 40, receiving a request to print a third report that accounts for the return on investment for a monetary amount spent on a drug sample distribution

program for a drug and the monetary amount received from prescriptions for the drug (see paragraphs 274-275).

As per claim 44, Feeney teaches:

The method of Claim 40, detecting fraud by comparing the drug sample quantity limit and the time frame in which the drug sample quantity limit is available to the prescriber and the claim data which is indicative of the number of pre-printed vouchers and print coupons redeemed by patients (see paragraphs 284-285)

As per claim 45, Feeney teaches:

The method of Claim 40, refining the drug sample quantity limit of the prescriber based on the number of redemptions of pre-printed vouchers and print coupons associated with the prescriber (see paragraph 282).

As per claim 51, Feeney teaches:

The system of Claim 1, wherein said fulfillment platform comprising:

A pharma rules sample engines for performing personalization and intelligent brand rule implementation (see paragraphs 37, 274-275);

A marketing sample engine for integrating with drug samples suppliers and Web portals for prescribers (see paragraphs 281-282) and

The pharma rules sample engine and the marketing sample engine being based on the set of brand rules and on a set of prescriber preferences (see paragraph 258-259).

As per claim 52, Feeney teaches:

The system according of claim 51, wherein the marketing sample engine links the drug sample fulfillment platform to one or more suppliers and drug samples so as to inhibit the lack of supply of sample drugs desired by the prescriber or inhibit the inconsistent supply of drug samples desired by the prescriber (see paragraph 259).

As per claim 53, Feeney teaches:

The system according to claim 6, wherein said fulfillment platform implementing a set of brand rules under which pharmaceutical drug samples are distributed, wherein said brand rules include: product; allocation quantity; sample type selected from a group consisting of live samples, pre-printed samples and on-demand samples; and, drug strength (see paragraph 275).

As per claim 54, Feeney teaches:

The system according to claim 6, wherein said fulfillment platform implementing a set of brand rules for distributing pharmaceutical drug samples, said brand rules including timing considerations that are selected from a group consisting of sample offer time limits and rolling expiration dates for vouchers from either within or between brands for which a quantity of drug samples can be ordered (see paragraph 275).

As per claim 55, Feeney teaches:

The system according to Claim 6, wherein said fulfillment platform comprising a pharma rules sample engine for implementation brand rules under which a prescriber may obtain drug samples, the pharma rules sample engine modifying the brand rules so as to change a quantity limit of drug samples to be distributed to the prescriber (see paragraph 282).

**Conclusion**

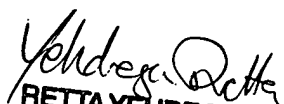
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL LASTRA whose telephone number is 571-272-6720. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ERIC W STAMBER can be reached on 571-272-6724. The RightFax number of the Examiner is 571-273-6720.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel Lastra  
May 9, 2005

  
RETTA YEHDEGA  
PRIMARY EXAMINER